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IN RE: REZULIN LITIGATION

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY

JAMES SCAVELLI,

Plaintiff,

v.

PFIZER, INC., WARNER-LAMBERT COMPANY, PARKE-DAVIS, a division of WARNER-LAMBERT; JANE/JOHN DOE A, B, C and D, and ABC Corporations 1-20, fictitious defendants,

Defendants.

DOCKET NO. MID L-011146-01 MT

CIVIL ACTION
CASE CODE: 246

MOTION TO SHOW CAUSE #0002

MARY CAVADA,

Plaintiff,

v.

PFIZER, INC., WARNER-LAMBERT COMPANY, PARKE-DAVIS, a division of WARNER-LAMBERT; JANE/JOHN DOE A, B, C and D, and ABC Corporations 1-20, fictitious defendants,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY

DOCKET NO. MID L-002156-01 MT

CIVIL ACTION
CASE CODE: 246

MOTION TO SHOW CAUSE #0003

Motion #: #
Judge: Cordeneus
Return Date: 7-19-02
Trial / Arb Date: _____
(circle one)
Submitted w/ Order: (yes) / no
(circle one)
JFlms

ALEJANDRO AMILL, Plaintiff, v. PFIZER, INC., WARNER-LAMBERT COMPANY, PARKE-DAVIS, a division of WARNER-LAMBERT; JANE/JOHN DOE A, B, C and D, and ABC Corporations 1-20, fictitious defendants, Defendants.	x SUPERIOR COURT OF NEW JERSEY : LAW DIVISION: MIDDLESEX COUNTY : : DOCKET NO. MID L-003694-01 MT : : CIVIL ACTION : CASE CODE: 246 : : **MOTION TO SHOW CAUSE** #0004
ROSE TRIGGS, Plaintiff, v. WARNER LAMBERT COMPANY, PARKE DAVIS, et al., Defendants,	x SUPERIOR COURT OF NEW JERSEY : LAW DIVISION: MIDDLESEX COUNTY : : DOCKET NO. MID L-008393-00 MT : : : : CIVIL ACTION : CASE CODE: 246 : : : **MOTION TO SHOW CAUSE** #0001

Plaintiffs hereby move for issuance of an Order to Show Cause why the Plaintiffs' Notice to Produce documents (Certification of Christopher A. Seeger, dated June, 26, 2002 ("Seeger Cert.") Exhibit 1) and as to why the Plaintiffs' Notice to Take the Oral Deposition (Seeger Cert. Exhibit 2) (collectively, "Plaintiffs' Notice") of a person knowledgeable with the Pfizer, Inc. ("Pfizer") acquisition of Warner-Lambert Company ("Warner-Lambert") should not be complied with by the defendants pursuant to Case Management Order No. 10. Defendants have objected to Plaintiffs' Notice on the grounds of relevancy and that Plaintiffs supposedly asserted that they

already had adequate discovery. Seeger Cert. Exhibit 3 (Letter from John F. Brenner to Arthur Penn, dated June 21, 2002). As discussed herein, defendants' objections are meritless and the Order to Show Cause should be issued.

This is critical discovery that has not yet been conducted in the MDL. Plaintiffs are bringing this Discovery in New Jersey because there is a pending trial date in New Jersey and, this discovery needs to be completed prior to the trial.[1] Plaintiffs have carefully and narrowly drafted to the discovery to address the issues in this case.

Specifically, Pfizer is the defendant in this case and will appear before the jury in this case. Pfizer took over WL through a hostile takeover. As a result, Warner Lamber merged into Pfizer. Pfizer began evaluating Warner Lambert for takeover before Rezulin was taken off the market. Pfizer either conducted some analysis of Rezulin or it didn't. Pfizer must have disclosed its analysis, or lack thereof, to its investor relations department and must have presented facts internally to investor relations, its Board of Directors and its scientists. Yet, none of this discovery has ever been produced.

As a preliminary matter, the jury needs to have explained why it is Pfizer is the defendant--therefore the general acquisition discovery. Moreover, since Pfizer is subject to punitive damages, Pfizer's conduct needs to be addressed in addition to the conduct of Warner Lambert specifically as it relates to Rezulin.

Pfizer is desperate to keep itself from being the subject of discovery. However, Pfizer reaped the benefits of the hostile takeover of Warner Lambert. Pfizer is the Defendant in this case. It cannot celebrate the hostile takeover; yet immunize itself from relevant discovery.

[1] The Plaintiffs in the California Coordinated Litigation have also requested similar relevant discovery from Pfizer. Pfizer has produced documents in California but no witnesses yet.

I. Defendants' Discovery Objections Are Unfounded

A. Plaintiffs' Seek Relevant Evidence

New Jersey Rule of Evidence 401 defines "relevant evidence" as "evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. New Jersey's discovery rules should be liberally construed to allow for expansive pretrial discovery. *See Payton v. New Jersey Tpk. Auth.*, 148 N.J. 524, 535 (1997) ("New Jersey's discovery rules are to be construed liberally in favor of broad pretrial discovery."); *see also Catalpa Inv. Group v. Franklin Tp. Zoning Board of Adjustment*, 254 N.J. Super. 270, 273 (Law Div. 1991) ("[P]retrial discovery is afforded the broadest possible latitude and extends not only to relevant information but also to any information that might lead to the discovery of relevant information."). Plaintiffs are entitled to discovery of any evidence that is "reasonably calculated to lead to the discovery of admissible evidence." *In re Liquidation of Integrity Ins. Co.*, 165 N.J. 75, 82 (2000).

Prior to the merger with Warner-Lambert, Pfizer performed due diligence to evaluate the value of Warner-Lambert. Factored into this evaluation was the safety and efficacy of Rezulin, as well as the potential benefit or liability posed by Warner-Lambert's marketing of the drug. In 1999-2000, while the merger was being considered and effected and Plaintiffs herein were still taking the drug, Rezulin had both earned over $1 billion for Warner-Lambert and been linked with severe hepatotoxic reactions in numerous patients. There can be no doubt that Pfizer reached a determination as to the effect Rezulin would have on the future value of the company after the merger.

B. The Challenged Discovery Is Necessary to Show Defendant Failed to Disclose Known Risks of Rezulin

The analysis made by Pfizer concerning Rezulin is relevant, admissible evidence, and is likely to lead to the discovery of additional relevant evidence. One overriding issue in this litigation is Warner-Lambert's knowledge of the relative risks and benefits of Rezulin, including the severity and frequency of incidents of Rezulin toxicity, in contrast to the information actually disclosed by Warner-Lambert about the risks of Rezulin. The determination Pfizer reached as to the value that Rezulin added to or subtracted from Warner-Lambert, as well as the materials Pfizer reviewed to reach that conclusion, are likely to prove probative to this issue. *See Simon v. Graham Bakery*, 17 N.J. 525, 530 (1955) ("It is well settled that the relevancy of testimony must be tested by its probative value with respect to its points at issue."); *see also Manieri v. Volkswagenwerk A.G.*, 151 N.J. Super. 422, 429 (App. Div. 1977).

The discovery undertaken to this point has revealed that throughout the approval and marketing process, defendants failed to warn doctors and patients of known risks of severe liver damage. Several instances have been established in which Warner-Lambert failed to disclose the information it had regarding the risks and benefits of Rezulin, including the following examples:

- The final FDA report prepared by Dr. David Graham estimated that "1-2 out of every 1,000 patients (1/500 – 1/1000) who use [Rezulin] for one year will die of [acute liver failure]." Seeger Cert. Exhibit 4 (Report of Dr. David J. Graham, dated December 19, 2000, at 17). The information relied upon by Dr. Graham included defendants' own pre- and post-marketing clinical studies and adverse event reports. This information was not disclosed to the medical community by Warner-Lambert.

- As early as 1997, Warner-Lambert's business partner, Glaxo Wellcome, withdrew Rezulin from the market in the United Kingdom and throughout Europe because Glaxo concluded, based upon information provided by Warner-Lambert, that the rate of serious liver injury could be as high as 1 in 300 patients. Seeger Cert. Exhibit 5 (Letter from Richard Sykes to Yoshihumi Kawamura, dated December 5, 1997, at ¶2). Despite this information, Warner-Lambert told doctors that Rezulin was actually safer than was suggested by the FDA. Seeger Cert. Exhibit 6 (Memorandum from M. Chan dated May 7, 1999, at 1).

- In a 1997 safety update issued by Warner-Lambert to the FDA (incidentally, Dr. Misbin testified that he relied upon this report in approving the monotherapy indication for Rezulin), defendants listed four patients from Rezulin clinical trials that were withdrawn due to elevated enzyme levels. The report stated that none of the four patients had enzyme elevations that exceeded two to three times the upper limits of normal. Seeger Cert Exhibit 7 (1997 Safety Update, dated May 23, 1997, at Bates No. NDAX0183417). Dr. Robert Misbin, the medical officer for the FDA in charge of Rezulin, reviewed defendants' data and discovered that contrary to Warner-Lambert's statements, one patient had an ALT level of 1111, and another had an ALT level of 181 (normal ALT levels range from approximately 30-45). Furthermore, there were twenty patients with enzyme levels greater than three times the upper limits of normal who were withdrawn but not mentioned in the safety update. Seeger Cert. Exhibit 8 (Letter from Dr. Robert Misbin to Mary Taylor, dated October 22, 1997, at 1). Defendants failed to provide an explanation for the glaring errors, merely replying, "The statement that LFT elevations did not exceed 3 times the upper limit of normal is not correct." Seeger Cert. Exhibit 9 (Parke-Davis FDA contact sheet, dated October 23, 1997, at Bates No. REGB0001033).

- The NIH conducted a clinical trial for Rezulin as part of a diabetes prevention program. Audrey Jones, an otherwise healthy patient who did not even suffer from diabetes, died from liver failure while on the drug. A distinguished panel of three doctors were convened to examine and determine the cause of Audrey Jones's death. The three doctors assembled by the NIH prepared a report attributing the cause of Ms. Jones' death to Rezulin. Seeger Cert. Exhibit 10 (Report of the Committee of Hepatic Injury regarding Patient #172079, at Bates No. PJSM-001-1759, ¶3). Warner-Lambert, however, ignored the findings of the three doctors and issued a press release stating that Audrey Jones's death was unrelated to Rezulin. Seeger Cert. Exhibit 11 (Warner-Lambert press release dated June 5, 1998, at 1).

- The Rezulin package insert stated that 48 patients were withdrawn from clinical trials due to elevated liver enzymes. Seeger Cert. Exhibit 12 (Rezulin package insert, June 1999, at 1). The label, however, was indisputably false. The actual number of patients withdrawn from clinical trials, as Warner-Lambert knew, was actually much higher than 48. Seeger Cert. Exhibits 13, 14 (E-mail from Randall Whitcomb to Donald Sizemore, dated January 7, 1998; JOB 105, dated October 23, 1997, at BCRS-022-0404-0407).

- After the need for a revised Dear Doctor letter warning physicians of the risks associated with Rezulin arose, Mark Askine of the FDA drafted a Dear Doctor letter that warned of enzyme elevations as high as thirty times the upper limits of normal. Seeger Cert. Exhibit 15 (Letter from Mark Askine to Mary Taylor, dated July 22, 1998, at 3). Parke Davis deleted this information in its final draft of the letter. Seeger Cert. Exhibit 16 (Fax from Mary Taylor to Mark Askine, dated July 22, 1998, at Bates No. DRMR-007-0872). Observing Parke Davis's seletions, Dr. Misbin criticized Parke Davis as "clearly unwilling to inform physicians about the grossly elevated liver enzymes which occurred during clinical trials." Seeger Cert. Exhibit 17 (E-mail from Robert Misbin to Mark Askine, dated July 22, 1998).

Overall, defendants' reluctance to share its knowledge of the risks of Rezulin with the medical community is a central issue to this case. Plaintiffs are entitled to review any material likely to reveal the true extent of defendants' knowledge of the dangerous effects of Rezulin.

Plaintiffs' supplemental discovery request also included requests for information unrelated to the merger or Pfizer's analysis of Warner-Lambert in connection with the same, and is beyond any relevancy objections raised by defendants. For example, Plaintiffs requested "[a]ny and all Documents received or in possession of Warner-Lambert's investor and/or shareholder relations department or group that relate in any way to Rezulin," and "[a]ny and all Documents received and/or created by any person on the Board of Directors for Warner-Lambert that relate in any way to Rezulin" (Exhibit 1). Defendants raise no specific objection to the production of such information, and no such objection exists. Defendants' refusal to produce any documents under the blanket objection of relevance should not be accepted.

II. Plaintiffs' Requested Discovery Is Not Time-Barred

Defendants further objected to Plaintiffs' Notice because Plaintiffs had supposedly taken the position that they had adequate discovery from defendants to permit them to try the cases. This assertion is baseless and should not be countenanced. Case Management Order No. 10 ("CMO 10") provides that, "[f]act discovery is continuing and shall close on July 15, 2002." (CMO 10 ¶7). As such, Plaintiffs are entitled to continue to request relevant evidence from defendants, regardless of whether they have sufficient discovery to try the case.

Furthermore, CMO 10 instructs that Plaintiffs may seek fact discovery of topics and information not previously produced in other Rezulin litigation. The discovery sought by Plaintiffs in Plaintiffs' Notice are novel areas of discovery that comply with the guidelines of

CMO 10. Consequently, defendants should produce the documents and persons sought by Plaintiffs.

CONCLUSION

For all of the reasons stated herein, an Order to Show Cause as to why the Plaintiffs' Notice should not be complied with by the defendants pursuant to Case Management Order No. 10 should be issued.

Dated: June 26, 2002

Respectfully submitted

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By: _____

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